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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,696	07/01/2004	Yoon-Won Kim	7037-69151-01	3101

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EXAMINER

BLUMEL, BENJAMIN P

ART UNIT

PAPER NUMBER

1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/500,696

Applicant(s)

KIM ET AL.

Examiner

Benjamin P. Blumel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 4-9, 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/1/04 and 9/17/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of invention I in the reply filed on February 13, 2007 is acknowledged. The traversal is on the ground(s) that a lack of unity has not been proven between the claimed inventions because the invention is not an antibody is not found persuasive because invention I is does not recite that limitation and the properties of invention I are not distinct over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-9, 11 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 13, 2007.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 17, 2004 and July 1, 2004 were filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claims 3 is objected to because of the following informalities: the listing of “*Orthomyxoviridae, Picornaviridae, Retroviridae* or *Herpes*” as genuses of viruses in line

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3 is incorrect. Proper viral taxonomy requires that viral families to end in *-idae*, where as genres are required to end in *-virus*. Appropriate correction is required based on presently accepted viral taxonomy classification.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kim et al. (Molecules and Cells, 1997).

The claimed invention is drawn to an isolated viral suppressing factor (VSF) protein with antiviral activity that is not a cytokine such as Interferon, and is produced by an immune cell stimulated by EMC-DV. The VSF protein has a H polypeptide of SEQ ID NO: 2, which is encoded by SEQ ID NO:1 and a L3 polypeptide of SEQ ID NO: 4, which is encoded by SEQ ID NO:3. The H polypeptide is about 55kDa, the L3 polypeptide is about 25kDa and the polypeptides L1 and L2 are about 30kDa each, which combine for a total weight over 100kDa. The VSF proteins antiviral activity suppresses

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the proliferation or replication of a virus belonging to the families *Orthomyxoviridae*, *Picornaviridae*, *Retroviridae* or a herpes virus, and has the ability prevent or treat viral infections.

“[A] prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it.” See *In re Oelrich*, 666 F.2d at 581. Additionally, the courts have determined that “[I]nherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art.” See *Mehl/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). That is, it need not have been appreciated or recognized that the prior art reference inherently discloses the same invention for the reference to be anticipatory. See *Mehl/Biophile Int’l Corp. v. Milgraum* 192 F.3d 1362, 1365 (Fed. Cir. 1999); *Atlas Power Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

In the instant case, Kim et al. teach the isolation a viral inhibitory substance (VIS) released by a splenocyte-myeloma-hybridoma following activation by (EMC-D virus). Kim et al. disclose that VIS is not an immunoglobulin or a cytokine, such as IFN. Furthermore, Kim et al. characterize the isolated VIS by testing its ability to inhibit diabetes development from EMC-D infection in mice, and its ability to interfere with *in vitro* plaque assays. Kim et al. also disclose that the VIS is protease susceptible, nuclease resistant, stable between a pH range of 5-9, and maintained inhibitory activity following a 10 minute, 37°C heat treatment. Kim et al. also discuss that the VIS is composed of at least two components based on their observations. Therefore, even though Kim et al. did not determine the sequence of the components of VIS, the teachings of *In re Oelrich*, *Mehl/Biophile Intn’l Corp.*, and *Atlas Power Co.* would support the isolated VIS complex of Kim et al. as anticipating the claimed invention of the instant application even though certain limitations were not expressly disclosed by Kim et al. In addition, the conclusion of *In re Crish* 393 F3d 1253, 1364 (Fed. Cir. 2004) states that the “discovery of new properties of a known material does not make claims reciting those properties novel”.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of EMC-DV induced diabetes development in mice, does not reasonably provide enablement for preventing and/or treating all viral infections claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered.

The claimed invention is drawn to a pharmaceutical composition of a VSF protein that is capable of preventing or treating viral infection. Some specific viruses are from the families *Orthomyxoviridae*, *Picornaviridae*, *Retroviridae* or a Herpes virus, but no known vaccines exists for viruses from such taxonomic groupings or of herpes viruses. Cintra et al. (Journal of Pediatrics, 2006) teach treating children with multivalent influenza vaccines (an *Orthomyxoviridae* virus), but in no instance was influenza virus

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infection prevented among their test groups. Barnard D. (Current Pharmaceutical Design, 2006) teaches that drugs are being utilized in the treatment of various viruses from the *Picornaviridae* family since effective vaccines have not been developed, therefore, such viral infections have yet to be prevented. Letvin N. (Nature, 2006) teaches some advances in understanding the behavior of HIV (a *Retroviridae* virus) infections, but current vaccines possess transient effectiveness towards treating HIV infections and do not prevent such an infection. Additionally, Pepose et al. (American Journal of Ophthalmology, 2006) teach vaccines for HSV 1 and 2 have not been able to provide protection against viral infections, which has been attributed to the ability of HSV to remain dormant *in vivo* and thus establish latent infections but evading the immune system. Therefore, in view of the teachings above, the amount of experimentation necessary to develop a vaccine capable of preventing or even treating viral infections of the claimed invention is considerable. In addition, the working examples provided focused on *in vitro* or *in ovo* tests when determining the antiviral properties of the VSF protein. Furthermore, the ability of the claimed VSF protein to prevent or treat a viral infection of a virus unrelated to EMC-DV is also questionable since the VSF protein would interact with EMC-DV and related variants, because of its physical similarities with antibody segments and since it was produced a hybridoma.

For the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed composition.

Summary

No claims are allowed.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Blumel whose telephone number is 571-272-4960. The examiner can normally be reached on M-F, 8-4:30.

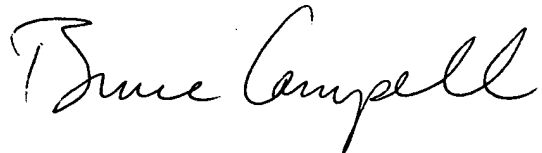
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Benjamin Blumel
Patent Examiner



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